

*Application No. 09/696378*  
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*Amendment*  
*Attorney Docket No. S63.2H-9503-US01*

*Remarks*

The specification has been amended to recite the proper chain of priority. US Patent Application Serial No. 09/426384, from which the present application claims the benefit, claims the benefit of US Patent Application Serial No. 09/257,677, now US Patent No. 6,284,333. No new matter has been added. For applications filed prior to November, 2000, this can be accomplished by amendment. See MPEP 201.11(E).

A telephone interview was conducted with Examiner Sow-Fun Hon on December 14, 2004. This amendment and response has been prepared in accordance with that telephone interview.

*New Rejections*

*35 U.S.C. §103(a)*

*Rau et al.*

Claims 1-2, 12-14, 19, 24, 31, 33 and 36 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rau et al. (WO 95/18647).

Independent claim 1 has been canceled and a new independent claim 37 has been added per the teleconference of December 14, 2004 with Examiner Sow-Fun Hon. Claim 31 has been amended in accordance with the teleconference as well.

Claims 2 and 12-14 have been canceled.

Claims 19 and 24 have been amended to depend from claim 37 and are patentable for at least the reasons that claim 37 is patentable.

Claims 33 and 36 depend from claim 31 and are patentable for at least the reasons that claim 31 is patentable.

Applicants have included information regarding the compliance of polyimide materials as discussed during the teleconference.

Polyimides, being relatively inelastic and hard materials are non-compliant polymeric materials. Applicants have enclosed a summary of physical properties for polyimide, available online from MatWeb, a copy of which is enclosed herewith. Compliance of balloon materials is discussed, for example, in commonly assigned U.S. Patent No. 5,556,383, a copy of which is enclosed herewith.

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The elongation at break for polyimide as found on page 2 of the polyimide overview is 4-10%. The hardness of polyimide, as measured using the Rockwell E hardness scale, is 50-99. The Rockwell hardness scales are employed for hard polymeric materials or metals while the Shore hardness scales are employed for polymeric materials. Applicants have included a summary from a webpage, <http://www.matweb.com/reference/rockwell-hardness.asp>, which discusses the Rockwell scales.

The properties of polyimide may be compared to polyethylene terephthalate, also known in the art as being non-compliant, has an elongation of 50% to 350% and a Rockwell Hardness of 110. A data sheet available online from MatWeb, has been enclosed herewith. See also commonly assigned U.S. Patent No. 5,556,383, enclosed herewith.

Applicants respectfully request withdrawal of the 35 U.S.C. §103(a) rejection over Rau et al. (WO 95/18647) and reconsideration of the claims as presented.

*Rau et al. in view of Zdrahala*

Claims 3-8 and 25-26 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rau as applied to claims 1-2, 12-14, 19, 24, 31, 33 and 36 above, and further in view of Zdrahala (US 5,248,305).

Claims 3-8 and 26 have been amended to depend from claim 37 which has been added per the teleconference of December 13, 2004. Claim 25 has been canceled. Claims 3-8 and 26 are patentable for at least the reasons that claim 37 is patentable.

Applicants respectfully request withdrawal of the rejection of claims 3-8 and 25-26 under 35 U.S.C. §103(a) as being unpatentable over Rau as applied to claims 1-2, 12-14, 19, 24, 31, 33 and 36 above, and further in view of Zdrahala, (US 5,248,305).

*Rau et al. in view of Zdrahala as evidenced by Yang (Polymer Data Handbook)*

Claims 15-18 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rau et al. as applied to claims 1-2, 12-14, 19, 24, 31, 33 and 36, above, and further in view of Zdrahala (US 5,248,305) as evidenced by Yang (Polymer Data Handbook).

Claims 15-18 have been amended to depend from claim 37 and are patentable for at least the reasons that claim 37 is patentable.

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Applicants respectfully request withdrawal of the rejection of claims 15-18 under 35 U.S.C. §103(a) as being unpatentable over Rau et al. as applied to claims 1-2, 12-14, 19, 24, 31, 33 and 36, above, and further in view of Zdrahala (US 5,248,305) as evidenced by Yang (Polymer Data Handbook).

*Rau et al. in view of Zdrahala as evidenced by Polymers (A Property Database)*

Claims 20 and 22-23 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rau et al. as applied to claims 1-2, 12-14, 19, 24, 31, 33 and 36, above, and further in view of Zdrahala (US 5,248,305) as evidenced by Polymers (A Property Database).

Claims 20 and 22-23 have been amended to depend from claim 37 and are patentable for at least the reasons that claim 37 is patentable.

Applicants respectfully request withdrawal of the rejection of claims 20 and 22-23 under 35 U.S.C. §103(a) as being unpatentable over Rau et al. as applied to claims 1-2, 12-14, 19, 24, 31, 33 and 36, above, and further in view of Zdrahala (US 5,248,305) as evidenced by Polymers (A Property Database).

*Rau et al. in view of Zdrahala as evidenced by Alger (Polymer Science Dictionary)*

Claim 21 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Rau et al. as applied to claims 1-2, 12-14, 19, 24, 31, 33 and 36, above, and further in view of Zdrahala (US 5,248,305) as evidenced by Alger (Polymer Science Dictionary).

Claim 21 has been amended and is now in independent form.

Claim 21 is directed to a dimensionally stable polymer balloon having a longitudinal axis and composed of micro-composite material, the micro-composite material comprising a polymer matrix component and a polymer fibril component distributed in the polymer matrix component, wherein the matrix component comprises a *polyamide-polyester block copolymer, a polyamide/polyether/polyester block copolymer, a polyester-polyether block copolymer, or a mixture thereof.*

As discussed above, Rau et al. disclose the incorporation of polyimide into balloons and/or shafts of a catheter.

Applicants submit that while Rau et al. discuss other balloon materials generally

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in the Background of the Invention, they fail to disclose the materials in combination with a fibril component, and they also fail to disclose the specific polymer materials recited in claim 21.

Zdrahala disclose catheter shafts or other extruded tubing of liquid crystal polymer plastic-containing material, but fail to disclose the use of such materials in balloons.

Applicants submit that Alger disclose Hytrel® as a polyether-polyester block copolymer, but do not disclose any uses for such a material.

Therefore, the combination fails to disclose balloons formed from the specific polymer materials recited in claim 21 in combination with a fibril component.

As the references fail to suggest all of the elements of claim 21 in combination, Applicants respectfully request withdrawal of the rejection of claim 21 under 35 U.S.C. §103(a) as being unpatentable over Rau et al. as applied to claims 1-2, 12-14, 19, 24, 31, 33 and 36, above, and further in view of Zdrahala (US 5,248,305) as evidenced by Alger (Polymer Science Dictionary).

*Rau et al. in view of Heino et al.*

Claims 8-11 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rau et al. as applied to claims 1-2, 12-14, 19, 24, 31, 33 and 36, above, and further in view of Heino et al. (US 6,221,962).

Claims 8-11 have been amended to depend from claim 37 which was added per the teleconference of December 14, 2004.

Claims 8-11 are patentable for at least the reasons that claim 37 is patentable.

Applicants respectfully request withdrawal of the rejection of claims 8-11 under 35 U.S.C. §103(a) as being unpatentable over Rau et al. as applied to claims 1-2, 12-14, 19, 24, 31, 33 and 36, above, and further in view of Heino et al. (US 6,221,962).

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### CONCLUSION

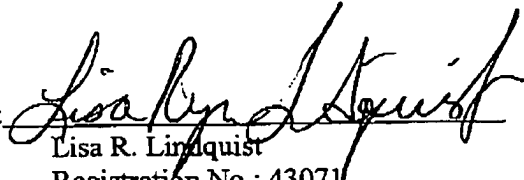
Claims 3-11, 15-23, 26, 31, 33 and 36-38 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011, to expedite prosecution of this application.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: December 14, 2004

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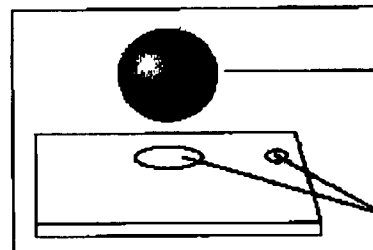
Searches: Sequential | Material Type | Property | Composition | Trade Name | Manufacturer

## Rockwell Hardness Testing of Plastics

The hardness testing of plastics is most often measured by the Rockwell hardness test or Shore (durometer) hardness. Both methods measure the resistance of the plastic toward indentation, thereby providing an empirical hardness value. Both hardness values do not necessarily correlate to other properties or fundamental characteristics. Rockwell hardness values are chosen for 'harder' plastics such as nylon, polycarbonate, polystyrene, and acetal where the resiliency or creep of the plastic is less likely to affect the results. The Barcol hardness test is sometimes chosen for thermoset polymers. The figure below, from Quadrant Engineering Plastic Products, shows the Rockwell hardness test geometry.

### ASTM D785:

A specimen of at least 1/4 inches (6.4 mm) thickness is indented by a steel ball. A small load is applied, the apparatus is zeroed, and then a larger load is applied and removed. After a short time with the preload still applied, the remaining indentation is read from the scale.



The results obtained from this test are a useful measure of relative resistance to indentation of various grades of plastic. However, the Rockwell hardness test does not serve well as a predictor of other properties such as strength or resistance to scratches, abrasion, or wear, and should not be used alone for product design specifications.

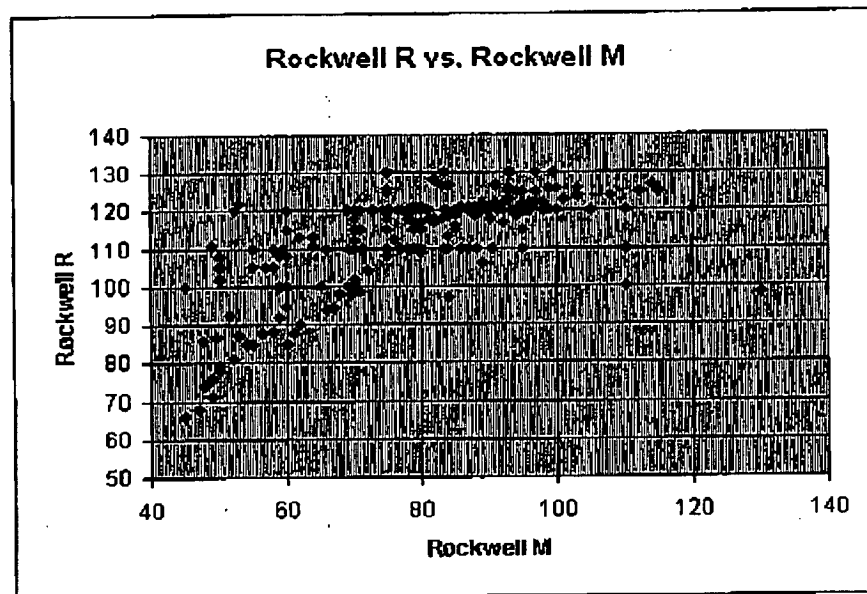
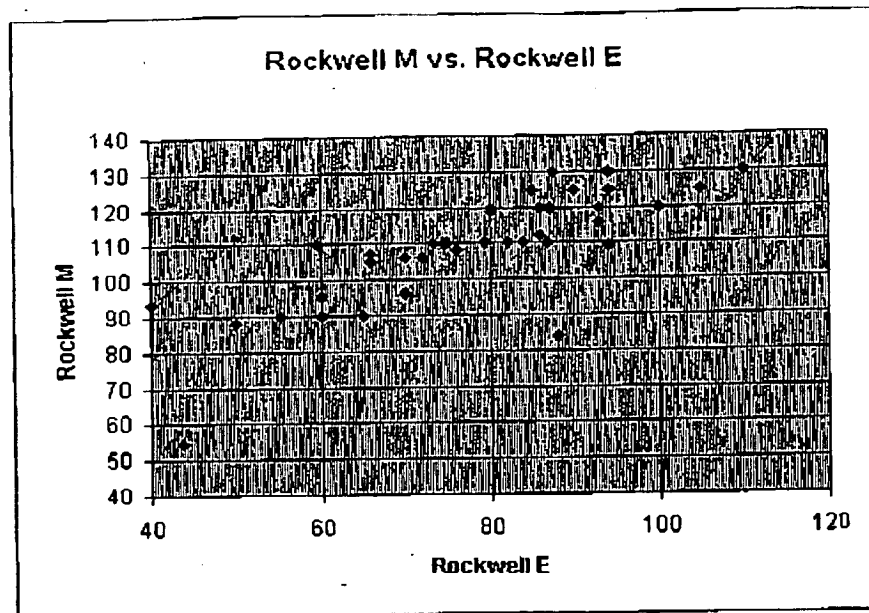
Different Rockwell hardness scales utilize different size steel balls and different loads. The three most common scales for plastics are Rockwell E, Rockwell M, and Rockwell R; results reported from the Rockwell L scale are much rarer. As shown in the charts below, the correlation between the Rockwell scales is weak; attempts at conversion between the scales are discouraged.

The charts below are taken from data in MatWeb's database provided by polymer manufacturers for specific products.

## Comparison of Rockwell Hardness Scales

## Rockwell Hardness Testing of Plastics

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## MatWeb.com, The Online Materials Database

### Overview - Polyimide

**Subcategory:** Polyimide; Polymer; Thermoplastic

**Close Analogs:**

Click button for specific proprietary grades that belong to this Overview class.

**Proprietary Grades**

Please be aware that some proprietary polymers may not be listed because they fall into more than one class or because of ambiguity in manufacturer's information.

**Key Words:** Plastics, Polymers

The property data has been taken from proprietary materials in the MatWeb database. Each property value reported is the average of appropriate MatWeb entries and the comments report the maximum, minimum, and number of data points used to calculate the value. The values are not necessarily typical of any specific grade, especially less common values and those that can be most affected by additives or processing methods.

Physical Properties	Metric	English	Comments
Density	1.34 - 1.43 g/cc	0.0484 - 0.0517 lb/in <sup>3</sup>	Average 1.4 g/ Gr Count :
Water Absorption	0.24 - 0.4 %	0.24 - 0.4 %	Average 0.31 Gr Count :
Moisture Absorption at Equilibrium	1.2 - 1.3 %	1.2 - 1.3 %	Average 1.2 Gr Count :
<b>Mechanical Properties</b>			
Hardness, Rockwell E	50 - 99	50 - 99	Average 74 Gr Count :
Hardness, Rockwell M	110	110	Gr Count :
Tensile Strength, Ultimate	72.4 - 120 MPa	10500 - 17400 psi	Average 94.2 MPa Gr Count :
Tensile Strength, Yield	120 MPa	17400 psi	Gr Count :
Elongation at Break	4 - 10 %	4 - 10 %	Average 7.2



Tensile Modulus	1.3 - 4 GPa	189 - 580 ksi	Average 2.5 GPa Count :
Flexural Modulus	2.482 - 4.1 GPa	360 - 595 ksi	Average 3.2 GPa Count :
Flexural Yield Strength	82.7 - 200 MPa	12000 - 29000 psi	Average 130 MPa Count :
Compressive Yield Strength	112.4 - 200 MPa	16300 - 29000 psi	Average 150 MPa Count :
Compressive Modulus	2.413 - 3.1 GPa	350 - 450 ksi	Average 2.6 GPa Count :
Poisson's Ratio	0.41	0.41	Count :
Fatigue Strength	44.8 MPa	6500 psi	Count :
Shear Strength	89.6 MPa	13000 psi	Count :
Izod Impact, Notched	0.4 - 0.75 J/cm	0.749 - 1.41 ft-lb/in	Average 0.53 J/cm Count :
Izod Impact, Unnotched	7.5 J/cm	14.1 ft-lb/in	Count :
Coefficient of Friction	0.29	0.29	Count :
K (wear) Factor	50	50	Count :
Limiting Pressure Velocity	0.35 MPa-m/sec	9990 psi-ft/min	Count :
<b>Electrical Properties</b>			
Electrical Resistivity	5e+014 - 1e+016 ohm-cm	5e+014 - 1e+016 ohm-cm	Average 3E+ ohm-c Count :
Surface Resistance	5e+015 ohm	5e+015 ohm	Count :
Dielectric Constant	3.4 - 3.55	3.4 - 3.55	Average 3.5; Gra Count :

Dielectric Constant, Low Frequency	3.4 - 3.62	3.4 - 3.62	Average 3.5; Gra Count :
Dielectric Strength	22 - 27.6 kV/mm	559 - 701 kV/in	Average 2; kV/mm; Gra Count :
Dissipation Factor	0.0034 - 0.005	0.0034 - 0.005	Average 0.00; Gra Count :
Dissipation Factor, Low Frequency	0.0018 - 0.005	0.0018 - 0.005	Average 0.00; Gra Count :
<b>Thermal Properties</b>			
CTE, linear 20°C	45 - 90 $\mu\text{m/m-}^\circ\text{C}$	25 - 50 $\mu\text{in/in-}^\circ\text{F}$	Average 61.3 $\mu\text{m/}^\circ\text{C}$ ; Gra Count :
CTE, linear 100°C	50 - 54 $\mu\text{m/m-}^\circ\text{C}$	27.8 - 30 $\mu\text{in/in-}^\circ\text{F}$	Average 52 $\mu\text{m/r}^\circ\text{C}$ ; Gra Count :
Heat Capacity	1.13 - 1.2 J/g-°C	0.27 - 0.287 BTU/lb-°F	Average 1.2 J/g Gra Count :
Thermal Conductivity	0.1 - 0.35 W/m-K	0.694 - 2.43 BTU-in/hr-ft <sup>2</sup> -°F	Average 0.25 W/ K; Gra Count :
Maximum Service Temperature, Air	304 - 360 °C	579 - 680 °F	Average 340; Gra Count :
Deflection Temperature at 1.8 MPa (264 psi)	280 - 360 °C	536 - 680 °F	Average 340; Gra Count :
Glass Temperature	323 - 340 °C	613 - 644 °F	Average 330; Gra Count :
Flammability, UL94	V-0	V-0	Gra Count :
Oxygen Index	53 %	53 %	Gra Count :
<b>Processing Properties</b>			
Processing Temperature	320 °C	608 °F	Gra

Count :

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## MatWeb.com, The Online Materials Database

### Overview - Polyethylene Terephthalate (PET), Unreinforced

**Subcategory:** Polyester, TP; Polyethylene Terephthalate (PET); Polymer; Thermoplastic

**Close Analogs:**

Click button for specific proprietary grades that belong to this Overview class.



Please be aware that some proprietary polymers may not be listed because they fall into more than one class or because of ambiguity in manufacturer's information.

**Key Words:** Polyester; Plastics; Polymers

The property data has been taken from proprietary materials in the MatWeb database. Each property value reported is the average of appropriate MatWeb entries and the comments report the maximum, minimum, and number of data points used to calculate the value. The values are not necessarily typical of any specific grade, especially less common values and those that can be most affected by additives or processing methods.

Physical Properties	Metric	English	Comments
Density	1.3 - 1.33 g/cc	0.047 - 0.048 lb/in <sup>3</sup>	Average = 1.32 g/cc; Grade Count = 4
Water Absorption	0.15 %	0.15 %	Grade Count = 1
Linear Mold Shrinkage	0.006 cm/cm	0.006 in/in	Grade Count = 1
<b>Mechanical Properties</b>			
Hardness, Rockwell M	95	95	Grade Count = 1
Hardness, Rockwell R	110	110	Grade Count = 1
Tensile Strength, Ultimate	55 MPa	7980 psi	Grade Count = 1
Tensile Strength, Yield	50 - 57 MPa	7250 - 8270 psi	Average = 54.5 MPa; Grade Count = 4
Elongation at Break	50 - 350 %	50 - 350 %	Average = 130%; Grade Count = 4
Elongation at Yield	3.8 %	3.8 %	Grade Count = 3
Tensile Modulus	2.47 - 3 GPa	358 - 435 ksi	Average = 2.7 GPa; Grade Count = 4
Flexural Modulus	1 GPa	145 ksi	Grade Count = 1
Flexural Yield Strength	80 MPa	11600 psi	Grade Count = 1
Compressive Yield Strength	90 MPa	13100 psi	Grade Count = 1
Izod Impact, Notched	1.4 J/cm	2.62 ft-lb/in	Grade Count = 1
Charpy Impact, Unnotched	NB	NB	Grade Count = 3
Charpy Impact, Notched Low Temp	0.27 - 0.31 J/cm <sup>2</sup>	1.28 - 1.48 ft-lb/in <sup>2</sup>	Average = 0.29 J/cm <sup>2</sup> ; Grade Count =

3

Charpy Impact, Unnotched Low Temp	NB	NB	Grade Count = 3
Charpy Impact, Notched	0.38 - 0.49 J/cm <sup>2</sup>	1.81 - 2.33 ft-lb/in <sup>2</sup>	Average = 0.42 J/cm <sup>2</sup> ; Grade Count = 3

**Electrical Properties**

Electrical Resistivity	2e+015 ohm-cm	2e+015 ohm-cm	Grade Count = 1
Dielectric Constant	3	3	Grade Count = 1
Dielectric Strength	18 kV/mm	457 kV/in	Grade Count = 1
Dissipation Factor	0.02	0.02	Grade Count = 1

**Thermal Properties**

CTE, linear 20°C	73 - 92 µm/m-°C	40.6 - 51.1 µin/in-°F	Average = 79.2 µm/m-°C; Grade Count=4
CTE, linear 20°C Transverse to Flow	48 - 78 µm/m-°C	26.7 - 43.3 µin/in-°F	Average = 61.7 µm/m-°C; Grade Count=3
Thermal Conductivity	0.2 W/m-K	1.39 BTU-in/hr-ft <sup>2</sup> -°F	Grade Count = 1
Melting Point	243 - 250 °C	469 - 482 °F	Average = 250°C; Grade Count = 4
Maximum Service Temperature, Air	63 - 100 °C	145 - 212 °F	Average = 74°C; Grade Count = 4
Deflection Temperature at 0.46 MPa (66 psi)	68 - 72 °C	154 - 162 °F	Average = 69.7°C; Grade Count=3
Deflection Temperature at 1.8 MPa (264 psi)	63 - 100 °C	145 - 212 °F	Average = 74°C; Grade Count=4
Vicat Softening Point	74 - 76 °C	165 - 169 °F	Average = 75.3°C; Grade Count = 3
Glass Temperature	73 - 78 °C	163 - 172 °F	Average = 76.5°C; Grade Count = 4

**Processing Properties**

Processing Temperature	280 - 300 °C	536 - 572 °F	Average = 290°C; Grade Count = 4
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